Data Integrity Lead 80-100% (m/f/d)

Job Description Summary

Today, Lonza is a global leader in life sciences operating across three continents. While we work in science, there's no magic formula to how we do it. Our greatest scientific solution is talented people working together, devising ideas that help businesses to help people. In exchange, we let our people own their careers. Their ideas, big and small, genuinely improve the world. And that's the kind of work we want to be part of.

Data Integrity lead supports site management in strengthening the strategy at Lonza for Data Integrity.
Assists in global remediation project and acts as an SME regarding Data Integrity for the site Visp. The Data Integrity lead drives the site remediation efforts.
The Data Integrity lead is also involved in creating GMP documentation to complete the Data Integrity site remediation project .

Key responsibilities:

- Understand GxP data being captured at your site and how to protect it securely
- Ensure data quality and consistency within the site through monitoring
- Follow data integrity notification process when problems arise
- Assist site personnel with archiving and backup though sampling
- Meet stated Lonza requirements
- Meet stated regulatory requirements
- Reduce the risk of regulatory findings / observations related to data integrity (Data integrity is a top focus and top citation made in inspection reports and warning letters)
- Execute the Data Integrity Risk Assessment for your site
- Understand the issues and report findings
- Create Corrective and Preventative Actions against the assessment
- Follow data integrity remediation to closure
- Work with site personnel to continually identify and leverage opportunities to improve the quality of data management
- Participate in the Community of Practice Group to share approaches with similar sites with corporate/regulatory requirements
- Engage and Partner with other DI leads for Lessons learned and concerns
- Contribute in group tracking for DI issues
- Participate in Data Integrity training and suggest improvements
- Act as data integrity consultant to site personnel
- Participate in gap assessments to ensure regulatory findings at Lonza and in industry and are monitored and corrected

Key requirements:

- Bachelor's degree or its equivalent
- Significant experience in the GMP regulated pharmaceutical industry
- Profound knowledge in cGMPs and cGDP requirements and understanding of the regulatory process and requirements
- Broad knowledge in CSV, Data Integrity and related guidelines (21 CFR Part 11, EU GMP Annex 11, GAMP5 and the underlying principles of each)
- Experience in interaction with all kind of interfaces within the organization and with regulatory agencies (Swissmedic, FDA etc.)
- Auditing experience in GMP regulated environments
- Working knowledge within electronic quality management systems (DMS / Trackwise / SAP)
- Fluency in German and English

Every day, Lonza's products and services have a positive impact on millions of people. For us, this is not only a great privilege, but also a great responsibility. How we achieve our business results is just as important as the achievements themselves. At Lonza, we respect and protect our people and our environment. Any success we achieve is no success at all if not achieved ethically.